having to put additional coatings on the radioactive material to keep it in place. This is highly advantageous because the preferred forms of radioactive emitters for this application are beta-emitters, which are characterized by the fact that the radiation dose drops off sharply even a short distance from the emitter. As a result, it is very important to place the radiation emitter as close as possible to the treatment area to achieve the maximum effect of the radiation, to minimize unwanted irradiation of other organs, and to ensure a relatively even dose distribution throughout the treatment area in order to avoid hot spots that might lead to over radiation.

Thus, the bonding of the radioactive source strongly to the catheter permits simplification of the device, better placement of the radioactive material relative to the treatment area, more effective use of the radiation emitted by the radioactive material, a minimization of the risk to the patient due to unwanted radiation dose, and a simplification of the manufacture of the catheter, since no additional coatings or special chemicals are required. These numerous advantages of the apparatus of claim 1 render it clearly unobvious over the cited prior art.

Turning to the art, the Examiner relies on Dake et al. as disclosing a catheter for endoluminal radiation treatment having an elongate, flexible hollow body 12 with a radioactive source 14 located in the radioactive segment of the distal section 20 of the catheter. Dake et al. preferably employs the radioactive material in the form of pellets 14 of radioactive material included in a carrier 12. See col. 5, lines 18-24 of Dake et al. Dake et al. also states that,

> The radioactive means can be any nuclide. A preferred material is iridium 192. The radioactive means can be any shape and can be placed onto or into a carrier 12, or manufactured into the material of the carrier 12.

See col. 5, lines 19-22 of Dake et al. The Examiner then takes the position that it would be obvious to provide a coating on the surface of the catheter wherein the radioactive source is bonded to the distal section of the catheter with sufficient bond strength for proper adherence based on this teaching of Dake et al. The applicant disagrees with this conclusion for the reasons given below.

It is well-established that

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a

> reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.
>
> The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure.

M.P.E.P. § 2143, *citation omitted.* It is applicant's position that at least two limitations of claim 1 are not taught or suggested by Dake et al. First, the bonding of the radioactive material to a surface of the distal end of the catheter body is not taught or suggested by Dake et al. Second, the bonding of the radioactive material with sufficient bond strength such that it does not detach during normal use of the catheter is also not taught or suggested by Dake et al. Accordingly, since the primary reference lacks several elements of claim 1, the Examiner has not made out a case of *prima facie* obviousness.

More specifically, it is not clear from a reading of col. 5, lines 18-24 of Dake et al. that Dake et al. even contemplates application of the radioactive material to the catheter in the form of a coating. In fact, the language of Dake et al. appears to suggest otherwise. First, Dake et al. refers to the radioactive means as having a shape. Then, in the same sentence Dake et al. indicates that the radioactive means, having a shape, can be placed onto or into a tube 12. This appears to teach away from a coating since the fact that the radioactive means of Dake et al. has a shape prior to application onto or into the tube 12, necessarily requires that it be fabricated into that shape prior to its application onto or into the tube 12. This teaches away from a coating since the radioactive means would not have a shape until after it were coated onto a substrate.

Moreover, the word, "placed" does not suggest to a skilled person the application of a coating. For example, the definition of "place" is to put or set in a particular place, position, situation or relation. *Webster's Encyclopedic Unabridged Dictionary of the English Language,* Gramercy Books, New Jersey, 1996, p. 1478, copy enclosed. Thus, the word "placed" would also lead a skilled person away from using a coating in view of the teachings of Dake et al.

Also, the teachings of Dake et al. are consistent with commercial radioactive means available in the marketplace. For example, there are at least two different shaped radioactive seeds available in the marketplace, one of which is shown in Dake et al. as being the radioactive means placed into the tube 12. The second shape of radioactive seed is a hollow tubular seed such as that described in U.S. Patent no. 5,713,828. Such a hollow tubular seed can be placed

onto a tube 12, assuming that the tube 12 has a smaller diameter than inner the diameter of the hollow tubular seed.

The Examiner also takes the position that,

> It is well known that the attachment of one material to the surface of another material required proper bonding or adherence by ensuring sufficient bond strength to prevent subsequent separation of the materials. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have placed a radioactive source onto body 12 of the catheter of Dake et al. wherein the radioactive source is attached by bonding with sufficient bond strength for proper adherence.

See page 3 of the Office Action. However, Dake et al. does not even mention bonding a radioactive source to a catheter in any way and the only exemplified embodiment of Dake et al. does not bond a radioactive source to the catheter, but instead places the radioactive source inside the catheter without bonding.

Dake et al. is also insufficient since it does not teach or suggest to a skilled person how to bond a radioactive material to a catheter, nor does Dake et al. described how to bond the radioactive material to the catheter in a manner such that under normal conditions of use of the catheter, the radioactive material will not detach from the catheter. Thus, the skilled person would not know that this was a desirable objective and would not know how to achieve this objective in view of Dake et al.

Also, U.S. Patent no. 5,871,437 (Alt) contradicts the Examiner's position since Alt, desiring to treat restenosis, the same goal as in Dake et al, teaches that the skilled person should ensure that the radioactive material does not remain bonded to the stent but rather that the radioactive material is released into the body so that it can be excreted to thereby dissipate the radioactive material. Thus, at least Alt teaches the skilled person that bonding the radioactive material to a catheter in a manner whereby it does not detach from the catheter during normal use is undesirable. This is in direct contrast to the Examiner's position that it would be obvious to retain the radioactive material bonded to the catheter.

Thus, it is the applicant's position that it is not well known, as the Examiner suggests, to attach a radioactive material to a flexible catheter by bonding the radioactive material to the catheter in a manner whereby the radioactive material will not detach from

the catheter under normal conditions of use of the catheter. Should the Examiner intend to maintain this position, then the applicant requests that the Examiner present evidence showing that the features at issue are, in fact, well-known features of catheters employing radioactive materials pursuant to MPEP § 2144.03.

Claims 2-6 depend from claim 1 and are thus considered be patentable over Dake et al. for the same reasons as are given for claim 1 above. Neither U.S. Patent no. 5,302,168 (Hess) nor U.S. Patent no. 5,405,309 (Carden, Jr.) cures the deficiencies of Dake et al. discussed above. In addition, Carden, Jr. also tends to contradict the Examiner's position since Carden, Jr. states,

> Perhaps of greater concern in the difficulty in producing a carrier-free palladium 103 seed which is safe in case of a failure of the seed outer container, that is, a seed from which the palladium 103 cannot escape from its supporting medium inside the seed and migrate into the blood stream and/or normal tissue of patients treated in the event of such a failure.

See col. 1, lines 39-45 of Carden, Jr. This statement confirms that it is not a routine matter to bond a radioactive material to a support since Carden, Jr. indicates that despite the existence of carrier-free palladium–103 since 1950, as of 1993 when the Carden, Jr. application was filed, no seeds employing carrier-free palladium-103 had yet been fabricated, at least in part because of the problem of bonding the palladium-103 to a support so that it will not migrate into the blood stream. This also shows that, contrary to the Examiner's position, it is not well known to bond a radioactive material to a catheter in a manner whereby it will not detach from the catheter under normal conditions of use.

Favorable consideration and withdrawal of the rejections of claims 1-6 under 35 U.S.C. §103(a) is respectfully requested.

Claims 7-8, 12-13 and 15-16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Dake et al. in view of U.S. Patent No. 5,282,781 (Liprie). This rejection is respectfully traversed and reconsideration is requested for the reasons, which follow.

The present invention, as claimed in claim 7, relates to a catheter useful for radiation treatment of a body including an elongate, flexible catheter body and a radioactive source housed within a cavity in the distal section of the catheter body. A portion of the catheter body is removable to provide access to the cavity wherein the radioactive source is housed. In this manner, a simple, easy to use catheter is provided that can locate the radioactive source very close to the treatment area. This is highly advantageous because the preferred forms of

radioactive emitters for this application are beta-emitters, which are characterized by the fact that the radiation dose drops off sharply even a short distance from the emitter. As a result, it is very important to place the radiation emitter as close as possible to the treatment area to achieve the maximum effect of the radiation, to minimize unwanted irradiation of other organs, and to ensure a relatively even dose distribution throughout the treatment area in order to avoid hot spots that might lead to over radiation.

The Examiner takes the position that Dake et al. discloses provision of a plurality of cylindrical pellets 14 of radioactive material in the distal end of a catheter body 12. However, the Examiner admits that Dake et al. does not disclose that a portion of the catheter body is removable to provide access to the cavity wherein the radioactive source is housed. Instead, the Examiner relies on Liprie as teaching a wire assembly 10 having a hollow tube 12, which the Examiner says is a catheter-like body, and wherein a radioactive source is housed in a cavity in the distal end of the wire assembly 10 and a plug 27 is utilized for placement and containment of the source in the cavity.

The applicant disagrees with the Examiner's position on the basis that a skilled person, reading Liprie, would immediately know that the "hollow tube 12" is part of the wire assembly and is not part of the catheter disclosed in Liprie. For example, at col. 8, line 67 to col. 9, line 1, Liprie teaches that, "Among the components of the source wire 10 is a thin, continuous, elongate, flexible metal tube 12..." This is the hollow tube 12 referred to by the Examiner and thus Liprie makes it absolutely clear that the hollow tube 12 is part of the source wire 10. This is important in view of the disclosure in relation to Fig. 7 of Liprie since Fig. 7 of Liprie depicts the source wire 10 being advanced through an implanted catheter 75. See col. 18, lines 50-52 of Liprie.

This means that a skilled person following the teachings of Liprie would not arrive at the present invention as claimed in claim 7 of the present application since the skilled person would be taught to fabricate a separate source wire 10 for insertion through a catheter 75, such as the catheter of Dake et al., and not to provide a cavity in the distal end of the catheter itself for housing the radiaoactive material and provide a means for accessing the cavity as claimed in claim 7 of the present application.

Also, the applicant does not agree with the Examiner's position that, "it would have been obvious at the time the invention was made to provide a removable plug 27 [in Liprie] since it

has been held that constructing a formerly integral structure in various elements involves only routine skill in the art." The problem with this position is that the Examiner has cited no teaching, suggestion or motivation for a skilled person to provide a removable plug 27 in the device of Liprie. Thus, the Examiner has not set out a case of *prima facie* obviousness. Rather, the Examiner has alleged that because it is within the capabilities of a skilled person to construct a removable plug 27, it would be obvious to do so. This is not correct since the skilled person has no motivation from either Dake et al. or Liprie to provide such a removable plug.

Accordingly, since the skilled person following the teachings of Liprie would associate the radioactive material with a guide wire, rather than with the catheter, and the Examiner has presented no motivation for a skilled person to provide a removable plug 27 in the device of Liprie, favorable consideration and withdrawal of the rejection of claim 7 under 35 U.S.C. §103(a) over the combination of Dake et al. and Liprie is requested.

Claims 8-14 all depend from claim 7 and are thus considered be patentable over the combination of Dake et al. and Liprie for the same reasons as are given for claim 7 above. Neither U.S. patent No. 5,302,168 (Hess), U.S. Patent No. 6,353,682 (Leavitt et al.), nor U.S. Patent no. 5,405,309 (Carden, Jr.) cures the deficiencies of the primary references Dake et al. and Liprie and thus claims 9-14 are considered to be patentable over the cited prior art for the same reasons as claim 7. Favorable consideration and withdrawal of the rejections of claims 7-14 under 35 U.S.C. §103(a) is respectfully requested.

Claims 15-16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Dake et al. in view of Liprie and further in view of Hess. This rejection is respectfully traversed and reconsideration is requested for the reasons which follow.

Claim 15 relates to a catheter including an elongate, flexible catheter body and an elongate, flexible carrier. The elongate flexible carrier includes a radioactive source housed within a cavity in the distal end of the carrier. At least a portion of the flexible carrier is removable to provide access to the cavity wherein the radioactive source is housed and the flexible carrier is sized and has sufficient strength and flexibility to navigate a portion of the body so that the radioactive source can be positioned at a desired location for treatment. Finally, the device includes a retractable sheath comprising a radiation shielding material.

The Examiner relies on a combination of Dake et al. and Liprie as discussed above with respect to claim 7. Claim 15 is considered to be clearly patentable over a combination of Liprie

and Dake et al. for the reasons given above with respect to claim 7 and because claim 15 requires the presence of a retractable sheath comprising radiation shielding material.

The Examiner relies on Hess for the teaching of a device 10 including a retractable sheath or shield 24 that can be drawn back when the radiation source 30 is properly positioned.

However, the Examiner is relying on a combination of a catheter (Dake et al.) with a features taken from a wire assembly for use in combination with a catheter (Liprie) with features taken from a wire assembly for use without a catheter (Hess). This is important because a catheter and a guide wire are distinctly different devices used for distinctly different purposes. The Examiner has presented no evidence whatsoever that a skilled person would adopt features of a guide wire into a catheter or adopt features of a catheter into a guide wire. In fact, it is inappropriate to make such a combination since the skilled person is aware that catheters and guide wires are different devices used for different purposed and are subject to different design criteria.

The Examiner also alleges that it would be obvious to adopt the rather complicated and bulky structure of the Hess sheath into the Liprie device. The applicant disagrees since the skilled person would appreciate that inclusion of the complex, bulky sheath of the Hess device in the device of Liprie is likely to cause serious problems when one tries to feed the wire assembly of Liprie through a catheter.

In fact, Liprie expends a great deal of effort to ensure that the shape of the wire assembly is such that it will easily pass through the tight curves or kinks in the catheter. See e.g. col. 18, lines 43-50. For example, Liprie proposes several tip designs, which are directed to ensuring that the wire assembly can easily pass through a catheter. See e.g. plug 27 of Figs. 1-2, tip 70 of Fig. 5, tip 90 of Fig. 6, as well as the provision of balls 88 in Fig. 6. More importantly, Liprie suggests rounding off or tapering the tip of the composite source wire 15 to permit the device to navigate tight curves or kinks in a catheter. See col. 12, lines 21-19 of Liprie. In fact, Lipries states at col. 15, lines 30-45 that,

> "The extremely thin, flexible and high strength high dose composite source wire produced according to the present invention provides a consideration advantage for treatment of certain particularly remotely located cancers. For example, in the case of liver cancer and/or pancreatic cancer or related organ cancers, in vivo localized radiation treatment from within the cancerous mass has not been possible using heretofore available source wires. For such treatment it is necessary for the radioactive source to reach and then pass through a catheter

implanted in the biliary tract or bile duct, which is an extremely narrow passageway. Radioactive source wires produced by techniques taught by the prior art are too large and inflexible to pass through the duct, much less the even narrower passageway afforded by the catheter implanted therein."

In view of this disclosure, the skilled person would not be motivated to modify the Liprie device by addition of a complex, bulky sheath system as taught by Hess since then the Liprie device would no longer be suitable for its intended purpose of passing through extremely narrow passageways in the body. Accordingly, since the proposed modification of Liprie renders Liprie unsatisfactory for its intended purpose, it cannot support a rejection under 35 U.S.C. §103(a). See e.g. MPEP 2143.01 and *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). For these reasons, favorable consideration and withdrawal of the rejection of claim 15 is requested.

Claims 16-18 and 20 all depend from claim 15 and are thus considered be patentable over the combination of Dake et al., Liprie, and Hess, for the same reasons as are given for claim 15 above. Neither U.S. Patent No. 6,353,682 (Leavitt et al.), nor U.S. Patent no. 5,405,309 (Carden, Jr.) cures the deficiencies of the primary references Dake et al., Liprie and Hess. Thus claims 16-18 and 20 are considered to be patentable over the cited prior art for the same reasons as claim 15. Favorable consideration and withdrawal of the rejections of claims 15-18 and 20 under 35 U.S.C. §103(a) is respectfully requested.

Claims 21 and 25-27 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Dake et al. in view of U.S. Patent No. 5,498,227 (Mawad). This rejection is respectfully traversed and reconsideration is requested for the reasons that follow.

Claim 21, as amended, relates to a catheter attachment including a substrate; a radioactive source associated with the substrate, said radioactive source and substrate being positioned within a portion of the catheter attachment. The catheter attachment includes structure that cooperates with structure on a catheter for releasably attaching the catheter attachment to the catheter at or near the distal end of the catheter so that the catheter can be employed to position the radioactive source at a desired location for treatment.

The Examiner admits that Dake et al. does not disclose a catheter attachment provided with structure for attachment to a catheter. Thus, the Examiner relies on Mawad for teaching the provision of a distal radioactive segment 30 in the Dake et al. device. However, the Mawad device is a radioactive wire and not a catheter. A skilled person would not adopt the structure of

a radioactive wire to form part of a catheter since, as discussed above, wires and catheters are different devices used for different purposes and subject to different design criteria.

Also, the skilled person following the combined teachings of Dake et al. and Mawad would not arrive at the present invention, but instead would provide the radioactive wire of Mawad for use in combination with the Catheter of Dake et al. for delivery of the radioactive materal as part of the wire and not as part of the catheter, as in the present invention.

Claims 22-30 all depend from claim 21 and are thus considered be patentable over the combination of Dake et al., and Mawad, for the same reasons as are given for claim 21 above. Neither U.S. Patent No. 6,353,682 (Leavitt et al.), Hess nor Carden, Jr. cures the deficiencies of the primary references Dake et al., Hess and Gupta. Thus claims 22-30 are considered to be patentable over the cited prior art for the same reasons as claim 21. Favorable consideration and withdrawal of the rejections of claims 22-30 under 35 U.S.C. §103(a) is respectfully requested.

Claims 31 and 33-35 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Hess in view of U.S. Patent no. 5,645,529 (Fagan). This rejection is respectfully traversed and reconsideration is requested for the reasons which follow.

The Examiner relies on Fagan et al. as teaching that it is well-known that multi-lobed balloon catheters are utilized to prevent occlusion of the lumen in which they are inserted. Fagan et al. provides a balloon catheter that is formed from a plurality of balloons each of which can be inflated independently of the others. If less than all balloons are inflated, it is possible to allow blood to flow through the lumen of the catheter that corresponds to the uninflated balloon. However, this is different than the apparatus of the present invention.

More particularly, Fagan et al. provides several different balloons each of which must be connected to its own lumen to allow independent inflation of the balloons. The present invention, on the other hand, provides a balloon catheter that employs a balloon with a plurality of chambers connected to a single inflation lumen. Thus, the present invention provides an inflatable balloon catheter that does not occlude a vessel or lumen, that can be implemented using only a single fluid passage to the balloon. Claim 31 requires a single fluid passage to clearly distinguish the present device over the device of Fagan et al. This offers a far simpler device that can be fabricated to fit into smaller body passages since only a single inflation lumen is required.

The Examiner alleges that since Fagan et al. teaches that the multi-lobed balloons 6da, 6b, 6c, 6d and 7 can be inflated simultaneously, this necessitates a connection to a common fluid passageway. The applicant disagrees since it is possible to inflate the balloons simultaneously using a separate connection to each balloon and simply applying the inflation pressure from each separate connection simultaneously.

More importantly, however, the fact remains that Fagan et al. discloses a plurality of fluid chambers in connection with a plurality of fluid pathways for introduction and removal of fluid since Fagan et al. must have this plurality of fluid pathways to allow selective inflation of one or more of the balloons and Fagan et al. teaches that such selective inflation of one or more of the balloons is highly desirable in order to be able to focus the inflation pressure from the balloons in certain directions. See e.g. col. 3, line 61 to col. 4, line 14 of Fagan et al. As a result, it would not be obvious to modify Fagan et al. in order to arrive at the present invention since this would defeat the intended purpose of the Fagan et al. device by removing the ability to direct the inflation pressures of the balloons by selectively inflating them.

Accordingly, claim 31 is considered to be clearly patentable for at least these reasons. Favorable consideration and withdrawal of the rejection of claim 31 over Hess and Fagan et al. is respectfully requested.

Claims 33-35 all depend from claim 31 and are thus considered be patentable over the combination of Hess and Fagan et al. for the same reasons as are given for claim 31 above. Favorable consideration and withdrawal of the rejections of claims 33-35 under 35 U.S.C. §103(a) is respectfully requested.

With respect to claim 34, the Examiner took the position that,

> It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a radiation stable outer coating instead of a sheath since the examiner takes Official Notice of the equivalence of a sheath and a coating for their use in the art for the purpose of covering a surface...

Office Action at pages 9-10. The applicant disagrees with this statement because a coating is a permanent covering of a surface whereas a sheath can be a temporary covering that can be removed, for example, during treatment, and replaced, for example, after treatment. As a result, coatings and sheaths are not equivalent since sheaths allow significantly greater flexibility than coatings.

Favorable consideration and issuance of a Notice of Allowance is requested.

Respectfully submitted,

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REDLINE VERSION OF AMENDMENTS TO THE CLAIMS

25. (Amended) A catheter attachment as claimed in claim 21, wherein the radioactive source is bonded to a surface of the substrate of the catheter attachment with sufficient bond strength that under normal conditions of use of the catheter attachment, the radioactive source will not detach from the catheter ~~body~~attachment.

26. (Amended) A catheter attachment as claimed in claim 22, wherein the radioactive source is bonded to an external surface of the catheter ~~body~~attachment.

27. (Amended) A catheter attachment as claimed in claim 22, wherein the radioactive source is bonded to an internal surface of the catheter ~~body~~attachment.